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Filed : August 23, 2001

REMARKS

The foregoing amendments and the following comments are responsive to the objections and rejections set forth by the Examiner in the July 30, 2003 Office Action.

The Examiner objected to the drawings under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the jackscrew, hydraulic cylinder, hydraulic pressure supply, ridges, and electric motor must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claims 1-6, 8-14, and 15-17 are pending in this application. In particular, the Examiner rejected Claims 3, 4, 5, 9-11 and 16 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner further rejected Claims 3, 5, and 6 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner further rejected Claims 1, 2, 8, 9, 10, 11, 13, 15, and 17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,827,316 by Young et al. ("the Young patent"). The Examiner further rejected Claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Young in view of US Patent No. 5,868,711 to Kramer et al ("the Kramer patent"). The Examiner further rejected Claims 6 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Young in view of US Patent No. 5,314,435 to Green et al. ("the Green patent"). The Examiner further objected to the drawings under 37 CFR 1.83(a) as not showing every feature of the invention specified in the claims.

Applicant would like to thank Examiner Roberts for the interview extended to Applicant's representative, Karen Lenker, on 15 September 2003. During the interview, the Examiner agreed that the amendments to Claim 1 clarified the patentably distinguishing features of the invention. Accordingly, Applicant has also amended Claim 13 along the lines discussed in the interview. Reconsideration of the pending claims, as amended, is therefore respectfully requested.

THE SPECIFICATION

Applicant has amended the specification to conform with the numbering and structure set forth in Figures 1B, 6A, 6B, 7A, and 7B. Additionally, Applicant has corrected an incorrect identification number, 20, for the spring 22. Applicant

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respectfully submits that no new matter is being introduced by way of this Amendment and requests that the foregoing Amendment to the specification be entered and made of record.

RESPONSE TO DRAWING OBJECTIONS

The Examiner objected to the drawings under 37 C.F.R. § 1.83(a) because the drawing must show every feature of the invention. In particular, the Examiner notes that the drawings do not illustrate the jackscrew, hydraulic cylinder, hydraulic pressure supply, ridges and electric motor as set forth in Claims 3, 4, 5, 9, 10, and 11. Figure 1B has been amended as set forth in the attached document entitled "SUBMISSION OF SUBSTITUTE DRAWINGS FOR APPROVAL BY EXAMINER."

Figure 1B now indicates longitudinal ridges or edges **102** on the tapered tip. The longitudinal ridges **102** are supported in the originally filed specification. On page 12, lines 16 and 17, the specification states, "Longitudinal edges are optionally disposed on the conical surface of trocar or tip **18** to enhance tissue penetration". In addition, Claims 9, 10, and 11 of the originally filed application state:

9. The apparatus of claim 8 wherein said tapered tip or trocar includes axially disposed ridges to assist with tissue penetration.

10. The apparatus of claim 9 wherein said axially disposed ridges are sharp enough to cut tissue.

11. The apparatus of claim 9 wherein said axially disposed ridges are blunted.

Accordingly, Applicant respectfully submits that no new matter is introduced by the proposed drawing change to Figure 1B.

New Figures 6A and 6B indicate the jackscrew **102** and the motor **110** on the punch. The jackscrew is supported in the originally filed specification on page 11, lines 3 through 8. On page 11, lines 3 through 8, the originally filed specification states:

"In another embodiment, the function of the spring **20** is replaced by a threaded jackscrew assembly. The shaft **14** is threaded and engages mating threads on the handle **20**. By rotating the handle **20**, the cutter **12** is rotated and simultaneously advanced proximally or distally in a positive displacement fashion."

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The motor is supported in the originally filed specification on page 10, lines 1 through 8. On page 10, lines 1 through 8, the originally filed specification states:

"Alternatively, the handle **20** may be rotated by a motor or gear motor which is electrically powered by a battery disposed either external to or internal to the punch **10**. External battery power is delivered to the motor through a cable with a plurality of conductors. On and off operation of the motor is controlled through a switch on the punch knob **24** or the handle **20**, by a foot switch, or by a sound activated switch."

Accordingly, Applicant respectfully submits that no new matter is introduced by the new Figures 6A and 6B.

New Figures 7A and 7B indicate the hydraulic cylinder **106** and the hydraulic pressure supply **108**. The hydraulic cylinder and the hydraulic pressure supply are supported in the originally filed specification on page 11, lines 9 through 12. On page 11, lines 9 through 12, the originally filed specification states:

"In yet another embodiment, the function of the spring **20** is replaced by a hydraulic cylinder and hydraulic pressure source with a valve or switch to control pressure into said cylinder."

Accordingly, Applicant respectfully submits that no new matter is introduced by the new Figures 7A and 7B.

In addition, the drawing sheet numbering has been revised to reflect the new number of drawing sheets.

Accordingly, Applicant respectfully submits that no new matter is introduced by the proposed drawing changes and therefore respectfully request the Examiner to withdraw the objection to the drawings.

REJECTION OF CLAIMS 3, 4, 5, 9-11, and 16 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner rejected Claims 3, 4, 5, 9-11, and 16 under 35 U.S.C. § 102(b), first paragraph, as failing to explain how to implement a jack screw, ridges, or hydraulic drive. The specific rejections made by the Examiner, and Applicant's response to these rejections, are discussed below.

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Claims 3, 5, and 16

The specification on page 11 lines 3-8 describes an embodiment of the invention where the function of the spring is replaced by a threaded jackscrew assembly. In an embodiment of the jackscrew, as is well known to one of skill in the art of mechanical devices, the shaft and the handle are threaded and the shaft engages with the mating threads on the handle. When the handle is rotated, the cutter is advanced along the shaft, in addition to being rotated. This is illustrated in new Figures 7A and 7B.

The jack screw is a simple machine as is well known to one of skill in the art of mechanical devices. It is defined in the following Encyclopedia Britannica article: "Mechanical Efficiency." Encyclopedia Britannica. 2003. Encyclopedia Britannica Premium Service. 16 Sep, 2003 <http://www.britannica.com/eb/article?eu=52984>. In addition, Applicant searched the PTO patent database from 1976 to present and found 2160 hits for jackscrew or the alternative spelling jack screw.

Applicant believes Claims 3, 5, and 16 satisfy the enablement requirement to one of skill in the art, and Applicant respectfully request that the Examiner withdraw the rejection of Claims 3, 5, and 16 under 35 U.S.C. § 112, first paragraph.

Claim 4

The specification on page 11 lines 9-12 describe an embodiment of the invention where the function of the spring is replaced by a hydraulic cylinder and hydraulic pressure source. The hydraulic pressure source has a valve or switch to control the pressure. New Figures 7A and 7B illustrate the hydraulic embodiment of the invention. Applicant believes Claim 4 satisfies the enablement requirement.

Additionally, Applicant has withdrawn Claim 4 with the understanding that if a generic claim is found allowable, the species claims will also be allowable.

Thus, Applicant respectfully request that the Examiner withdraw the rejection of Claim 4 under 35 U.S.C. § 112, first paragraph.

Claims 9-11

The specification on page 12 lines 16-17 has been amended to include longitudinal edges or ridges 102. The originally filed claims 9-11 provide support for the addition of ridges 102 to the specification. The longitudinal edges or ridges are

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disposed on the conical surface of the trocar or tip to enhance tissue penetration. Applicant believes Claims 9-11 satisfy the enablement requirement, and Applicant respectfully request that the Examiner withdraw the rejection of Claims 9-11 under 35 U.S.C. § 112, first paragraph.

REJECTION OF CLAIMS 3, 5, and 16 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner rejected Claims 3, 5 and 16 under 35 U.S.C. § 102(b), second paragraph, as failing particularly point out and distinctly claim a jack screw and ridges.

Ridges or longitudinal edges are described in the specification on page 12 lines 16-17. The term "ridges" has been amended into the specification and is supported by originally filed claims 9-11.

Claims 3, 5, and 16

The specification on page 11 lines 3-8 describes an embodiment of the invention where the function of the spring is replaced by a threaded jackscrew assembly. In an embodiment of the jackscrew, as is well known to one of skill in the art of mechanical devices, the shaft and the handle are threaded and the shaft engages with the mating threads on the handle. When the handle is rotated, the cutter is advanced along the shaft, in addition to being rotated. This is illustrated in new Figures 7A and 7B.

The jack screw is a simple machine as is well known to one of skill in the art of mechanical devices. It is defined in the following Encyclopedia Britannica article: "Mechanical Efficiency." Encyclopedia Britannica. 2003. Encyclopedia Britannica Premium Service. 16 Sep, 2003 <http://www.britannica.com/eb/article?eu=52984>.

In addition, Applicant searched the PTO patent database from 1976 to present and found 2160 hits for jackscrew or the alternative spelling jack screw. Applicant believes that jackscrew is a well-known simple mechanical device in the art of mechanical devices.

Applicant believes Claims 3, 5, and 16 satisfy the statutory requirements for patentability. Withdrawal of the rejection of Claims 3, 5, and 16 under 35 U.S.C. § 112, second paragraph is requested.

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REJECTION OF CLAIMS 1, 2, 8, 9, 10, 11, 13, 15, and 17 UNDER 35 U.S.C. § 102(b)

The Examiner rejected Claims 1, 2, 8, 9, 10, 11, 13, 15, and 17 under 35 U.S.C. § 102(b) as being anticipated by Young. In view of the following discussion, Applicant respectfully traverses this rejection.

Claim 1

Young does not appear to disclose the use of an anvil where the anvil is at least as wide as the largest exterior cutting dimension of the cutter. Further, Young does not teach an anvil that serves as a positive stop for the cutter. In addition, Young does not teach a cutter that does not pass beyond the proximal surface of the anvil, nor does Young teach a cutter that, in its lowest energy state, rests against the anvil with a net compressive force.

Rather, Young appears to disclose an aortic punch 10, which includes a thumb button 12, a cutting blade 44, and an anvil 54, wherein the cutting blade 44 slides and rotates along with the hollow body member 34 in relation to the shaft 38 as the cutter 44 moves toward and across the anvil 54. In Figures 1a, 1b, 2a, 2b, 3, 4, 5a, 5b, and especially Figure 6, the anvil 54 is shown to have a smaller diameter than cutting blade 44. In several descriptions of the relationship between the cutting blade 44 and the anvil 54, (column 6, lines 20 to 26, for example) Young appears to state: "as the thumb button 12 is pushed, the hollow body member 34 slides and rotates along the shaft 38, and the cutter 44 on the hollow body member 34 slides towards, and rotates relative to, the anvil 54. As the thumb button 12 is more fully pushed, the cutter 44 rotates and **slides past the anvil 54** as shown in FIG 6, thus severing a portion 57 of the wall 56 of the aorta 58." Emphasis added.

In contrast, in at least an embodiment of the present invention, the anvil 16 is a flat surface disposed distally to the cutter 12 and aligned in a plane generally perpendicular to the axis of the shaft 14. The anvil 16 is at least as wide as the largest exterior cutting dimension of the cutter 12. In this way, the anvil 16 serves to positively stop the cutter 12. The cutter 12 is advanced against the anvil 16 during the cutting procedure. The cutter 12 does not pass beyond the proximal surface of the anvil 16. In

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its lowest energy or inactive state, the cutter 12 rests against the anvil 16 with a net compressive force and the spring 22 expanded to its maximum allowable amount. The compressive force between the closed cutter 12 and the anvil 16 serves to maintain contact between the surfaces and promote cutting at the end of the stroke. Further, Figures 1A and 1B of the invention, clearly show the cutter 12 as being smaller in diameter than the anvil 16 and the anvil 16 forming a positive stop so that the cutter 12 does not pass beyond the proximal end of the anvil 16. See page 13, lines 3-16 and Figures 1A and 1B.

In summary, Young's surgical punch uses a scissors motion to cut tissue such that Young's anvil passes by the cutter. In contrast, the Applicant's punch uses a positive stop for the cutter against the face of the anvil to cut tissue such that the cutter does not pass beyond the face of the anvil.

Because the Young reference does not disclose, teach or suggest the use of an anvil, wherein the surface of the anvil is perpendicular to the longitudinal axis of the shaft, wherein the anvil is at least as wide as a largest exterior diameter of the cutting blade, and wherein the cutting blade does not pass beyond the surface of the anvil; the Applicant asserts that Claim 1 is not anticipated by Young. Applicant therefore respectfully submits that Claim 1 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 1.

Claims 2, 8, 9, 10, and 11

Claims 2, 8, 9, 10, and 11, which depend from Claim 1 are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Claim 13

Young does not appear to disclose the use of an anvil where the anvil is at least as wide as the largest exterior cutting dimension of the cutter. Further, Young does not teach an anvil that serves as a positive stop for the cutter. In addition, Young does not teach a cutter that does not pass beyond the proximal surface of the anvil, nor does

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Young teach a cutter that, in its lowest energy state, rests against the anvil with a net compressive force.

Rather, Young appears to disclose an aortic punch 10, which includes a thumb button 12, a cutting blade 44, and an anvil 54, wherein the cutting blade 44 slides and rotates along with the hollow body member 34 in relation to the shaft 38 as the cutter 44 moves toward and across the anvil 54. In Figures 1a, 1b, 2a, 2b, 3, 4, 5a, 5b, and especially Figure 6, the anvil 54 is shown to have a smaller diameter than cutting blade 44. In several descriptions of the relationship between the cutting blade 44 and the anvil 54, (column 6, lines 20 to 26, for example) Young appears to state: "as the thumb button 12 is pushed, the hollow body member 34 slides and rotates along the shaft 38, and the cutter 44 on the hollow body member 34 slides towards, and rotates relative to, the anvil 54. As the thumb button 12 is more fully pushed, the cutter 44 rotates and **slides past the anvil 54** as shown in FIG 6, thus severing a portion 57 of the wall 56 of the aorta 58." Emphasis added.

In contrast, in at least an embodiment of the present invention, the anvil 16 is a flat surface disposed distally to the cutter 12 and aligned in a plane generally perpendicular to the axis of the shaft 14. The anvil 16 is at least as wide as the largest exterior cutting dimension of the cutter 12. In this way, the anvil 16 serves to positively stop the cutter 12. The cutter 12 is advanced against the anvil 16 during the cutting procedure. The cutter 12 does not pass beyond the proximal surface of the anvil 16. In its lowest energy or inactive state, the cutter 12 rests against the anvil 16 with a net compressive force and the spring 22 expanded to its maximum allowable amount. The compressive force between the closed cutter 12 and the anvil 16 serves to maintain contact between the surfaces and promote cutting at the end of the stroke. Further, Figures 1A and 1B of the invention, clearly show the cutter 12 as being smaller in diameter than the anvil 16 and the anvil 16 forming a positive stop so that the cutter 12 does not pass beyond the proximal end of the anvil 16. See page 13, lines 3-16 and Figures 1A and 1B.

In summary, Young's surgical punch uses a scissors motion to cut tissue such that Young's anvil passes by the cutter. In contrast, the Applicant's punch uses a

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positive stop for the cutter against the face of the anvil to cut tissue such that the cutter does not pass beyond the face of the anvil.

Because the Young reference does not disclose, teach or suggest advancing a cutting blade into a hollow organ or body vessel under controlled force until the cutting blade fully rests against a blunt surface of an anvil whose outside diameter is greater than or equal to the outer diameter of the cutting blade, wherein the blunt surface of the anvil is perpendicular to a longitudinal axis of the cutting blade, and wherein a leading edge of the cutting blade does not pass beyond the blunt surface of the anvil, the Applicant asserts that Claim 13 is not anticipated by Young. Applicant therefore respectfully submits that Claim 13 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 13.

Claims 15 and 17

By this amendment, Applicant has canceled Claims 15 and 17 without prejudice or disclaimer. Accordingly, Applicant respectfully requests the Examiner to withdraw the objection under 35 U.S.C. § 102(b).

REJECTION OF CLAIM 4 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Young in view of Kramer. In view of the following discussion, Applicant respectfully traverses this rejection.

Claim 4, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein. However, Applicant respectfully requests withdrawal of Claim 4 from consideration. Applicant respectfully requests the Examiner to withdraw the objection under 35 U.S.C. § 103(a).

REJECTION OF CLAIMS 6 and 12 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 6 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Young in view of Green. In view of the following discussion, Applicant respectfully traverses this rejection.

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Claims 6 and 12, which depend from Claim 1 are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

NEW CLAIMS

New Claim 19 has been added to clarify the orientation and positioning of components, proximally and distally, on the punch and is believed to be allowable for the same reasons as those for Claim 1.

New Claims 20 and 21 have been added to further define the Applicant's inventions. New Claims 20 and 21 further define the vent holes in the cutter.

New Claims 20 and 22-24 depend from new Claim 19 and are believed to be allowable for the same reasons articulated above with respect to Claim 19, and because of the additional features recited therein.

New Claim 21 depends from amended Claim 13 and is believed to be allowable for the same reasons articulated above with respect to Claim 13, and because of the additional features recited therein.

New Claims 19, 20, 21, 22, 23 and 24 have been added to more fully define the Applicant's invention and are believed to be fully distinguished over the prior art of record.

REQUEST FOR TELEPHONE INTERVIEW

Pursuant to M.P.E.P. § 713.01, in order to expedite prosecution of this application, Applicant hereby formally requests a telephone interview with the Examiner as soon as the Examiner has considered the effect of the arguments presented above. Applicant's representative may be reached by telephone at (949) 494-3645.

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CONCLUSION

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Examiner is cordially invited to contact the undersigned such that any remaining issues may be promptly resolved.

Respectfully submitted,

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By: Karen J. Lehker
Karen J. Lehker
Registration Number 54,618
408 Panorama Drive
Laguna Beach, CA 92651
(949) 494-3645